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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,302	03/27/2002	Stefan Hulsmann	SCHUB I	8375
23599	7590	07/19/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			WEBMAN, EDWARD J	
		ART UNIT	PAPER NUMBER	
			1616	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/937,302	HULSMANN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Edward J. Webman	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 33 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,6-13,15,17,19,20 and 22-32 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,6-13,15,17,19,20 and 22-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6, 10-13, 15, 17, 19-20, 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zettler et al in view of Budavari et al.

Zettler et al teach solid dosage forms comprising a drug made by extrusion (abstract). Polyvinylpyrrolidone is disclosed as a binder (column 3 line 48). Triglycerides are specified (column 4 lines 44-47). Estradiol and ethinylestradiol is disclosed (column 6 line 2). 0.1-95% active is specified (column 5 lines 25-26). Tablets are disclosed (column 8 line 64).

Budavari et al teach that desogestrel is used with estrogens in oral contraceptives.

It would have been obvious to one of ordinary skill to add desogestrel in the composition of Zeitler et al to achieve the beneficial effect of an oral contraceptive. As to the claimed extrusion without heat input, Zettler et al teach that heating can be done outside the extruder (column 3 lines 9-12). As to the claimed grinding, such would be an obvious expedient to make a granulate for tablets or capsules.

Applicants argue hindsight reconstruction, however, Zettler et al teach applicants' three classes of ingredients (compare applicants' active, extrusion additive, and adjuvant to Zettler et al's pharmaceutical active, flow promoter, and binder/plasticizer). Applicants argue picking and choosing, however, as asserted previously, Zettler et al

disclose that, for the purposes of their invention, the particular species are equivalent. Applicants argue there is no teaching of equivalency, however, the listing of suitable compounds for a particular class, for example, binders, indicates that all the compounds in the list are equivalent for the purpose of binding. Applicants argue that Zettler et al teach away from plasticizers, now citing *Alza Corp.* 73 USPQ2d 1161. However, as stated previously, the disclosure cites the absence of plasticizers as a preference, not a prohibition. Further, *Alza Corp.* refers to a “clear disavowal” of a compound, whereas here, Zettler et al merely refers to a preference.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 13, 17, 19-20, 22-24, 26-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Meignant.

Meignant teaches a composition comprising estradiol, polyethylene glycol and solid triglycerides (column 6 lines 15-20).

Applicants now argue that Meignant teach micronized estradiol. However, it appears that micronization is merely a preference(see column 2 line 50 “free or

vectorized micronized" and claim 1 versus claims 19-20). Further, "micronized" may be interpreted as a process limitation. Such limitations are not considered patentable during prosecution of composition claims before the USPTO.

Claims 1, 4, 6, 8, 13, 17, 19-20, 22-24, 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al.

Rosenberg et al teach a melt-extruded drug form (abstract). Good thermoplasticity is specified (column 1 line 56). Glycerol tribehenate (column 2 line 23) and polyvinylpyrrolidone (column 2 line 26) are disclosed. Any drug under the conditions of melt extrusion is specified (column 2 lines 49-50). Extrusion at 50 degrees Centigrade is disclosed (column 2 line 63). Tablets are specified (column 3 line 3).

The examiner takes notice under MPEP 2144.03 that estradiol has a melting point of 173-179 degrees Centigrade.

It would have been obvious to one of ordinary skill in the art to deliver estradiol in the vehicle of Rosenberg et al to achieve the beneficial effect of a vehicle with good thermoplasticity and in view of the fact that the melting point of estradiol is such that it will not decompose under the conditions of extrusion Rosenberg et al specify.

Claims 1, 4, 6-7, 9-13, 15, 17, 19-20, 22-24, 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al.

Appel et al teach a controlled release dosage form which extrudes part of the core (abstract). Polyvinylpyrrolidone is disclosed (column 9 line 4). Saccharose

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monopalmitate is specified (column 12 line 13, see also column 15 line 64). Tablets are disclosed (column 3 line 25). Low-solubility drugs are specified (column 6 line 5 et seq.).

The examiner takes notice under MPEP 2144.03 that estradiol is almost insoluble in water.

It would have been obvious to one of ordinary skill in the art to achieve deliver estradiol in the vehicle of Appel et al to achieve the beneficial effect of controlled delivery and in view of the fact that the solubility of estradiol is such that it meets the design criteria for the vehicle.

Claims 1, 4, 6-13, 15, 17, 19, 22, 24, 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 26 "obtainable" is vague; it is unclear as to whether what follows is definitely claimed. See claim 20. In claim 28 "an polyvinylpyrrolidone" is indefinite. Is "a" intended? Claims 28-29 do not end with a period.

Claims 1, 4, 6-13, 15, 17, 19-20, 22-32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646 . The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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